

# BTL-2000 Series

USER'S MANUAL & USERS'S GUIDE

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#### 1 GENERAL CHARACTERISTICS

BTL-2000 is a portable therapeutic laser that employs red and infrared BTL laser probes of various powers.

BTL-2000 is designed for easy use and is understandable even for those who are new to laser technology. The laser beam irradiation strength is easy to regulate. Parameters can easily be changed as desired and your own programmes can be created and saved. BTL-2000 software allows continuous change of frequency, density, power, area and time. Considering all parameters are correlated, when a parameter is changed the instrument automatically recalculates the remaining parameters.

BTL-2000 provides preset programmes for the following medical fields: rehabilitation, orthopaedics dentistry, gynaecology, neurology, dermatology, ENT, sports medicine, paediatrics, and general practice. The use of the preset programmes can significantly speed up therapy. When a field and diagnosis is chosen, the instrument will automatically set up the therapy parameters.

BTL-2000 excels with its high power and operates in both Continuous and Pulse modes. In the pulse mode it is possible to modify the DUTY FACTOR of output frequency in the range of 10–90 %. BTL-2000 enables the user to precisely determine the necessary probe distance from skin by setting the desired therapy surface area. BTL-2000 automatically tests laser probe performance and corrects the power for optimal laser output. BTL-2000 is compatible with both digital and analog probes.

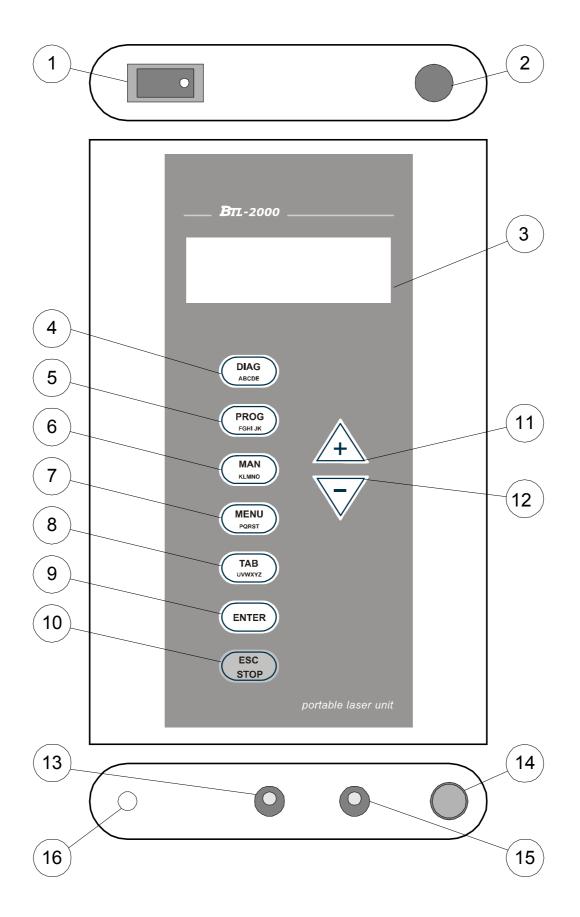
BTL-2000 is especially suitable for acupuncture treatment. BTL-2000 has two modes for easy and percise location of acupuncture points. While the instrument measures the changes in skin resistivity, visual and accoustic signals indicate acupuncture point locations. The instrument is also pre-programmed with Nogier and EAV frequencies.

For dentistry, gynaecology and ENT special optical attachments enable the laser to treat difficult to reach places. The optical attachments are easily attached to the probe and ready for use.

BTL-2000 complies with all internationally recognised laser instrument specifications.

## 2 USER MANUAL

# **Upper Panel, Front Panel, Lower Panel**



#### 2.1.1 Outward Appearance

BTL-2000 is housed in a metal varnished box. Weight and measurements are described in Technical Parameters 3.

The lighted LCD display and push buttons are located on the front panel. Laser probe connector and mains power switch are located on the upper panel. Connector for mains power/recharge adapter (CHARGE) cable, acupuncture probe connector (ACUPUNCTURE), connector for remote blocking (REMOTE CONTROL) and input for measuring laser power (PROBE TEST) are located on the lower panel.

Voltage converter switch (115/230) and mains power plug are located on the mains power adapter (BTL-282).

Manufacturer label and product label are located on the rear panel of the instrument case and mains power adapter.

Warning labels are located on the rear and upper panels of the instrument case and on the laser probe.

#### 2.1.2 Functions of Push buttons, Connectors, and Display.

- 1. Mains Power Switch
- 2. Laser Probe Output
- LCD display
- 4. [DIAG] push button enters Medical Field Menu.
- **5. [PROG]** push button enters Preset Programme Menu.
- **6. [MAN]** push button sets therapy parameters for manual programming.
- 7. **[MENU]** push button returns instrument to System Menu.
- **8. [TAB]** push button moves cursor to right when entering Safety Code, selects parameter settings **[MAN]**, and moves cursor between medical field number and diagnosis number **[PROG]**.
- **9. [ENTER]** push button confirms selection, setting changes and safety code.
- 10. [ESC/STOP] push button terminates therapy, starts/stops timer, and returns display to previous setting.
- 11. [+] push button increases parameter values, selects settings, and moves cursor to the right.
- 12. [ ] push button decreases parameter values, selects settings and moves cursor to the left deleting previous character.
- 13. Connector for mains power/ recharge adapter cable (CHARGE).
- **14.** Probe Test: Laser Optical Power Meter (TEST).
- **15.** Acupuncture Probe Input (ACUPUNCTURE).
- **16.** Remote Control Connector (DOOR).

#### 2.1.3 Basic Operation Procedures

BTL 2000 is controlled by means of an interactive menu. Press the [+] or [-] push buttons to move between menu settings. The selected setting is indicated by an arrow in the display's left margin. The presence of an additional arrow indicates that the menu exceeds four lines when selecting the last setting on the display. Press [ENTER] to confirm selected setting. Press [ESC/STOP] to return to previous menu.



The lower margin of the push buttons contains a set of letters. For entering letters, choose the desired letter by the number of push button presses relative to the placement of that character on the push button. For example in the figure above, U is entered by pressing the **[Tab]** push button once, V is entered by pressing the **[Tab]** push button twice, etc..

11 characters can be entered using each lettered push button. For entering non letter characters, choose the desired character by the number of push button presses relative to the placement of that character in the table below. For example in the figure below, "!" is entered by pressing the **[Tab]** push button nine times, "?" is entered by pressing the **[Tab]** push button ten times, etc..

DIAG	Α	В	С	D	Е	1	2	-	,	:	;
PROG	F	G	Н	I	J	3	4	+	-	*	/
MAN	K	L	М	Ν	0	5	6	(	)	<	>
MENU	Р	Q	R	S	Т	7	8	@	#	\$	&
TAB	U	V	W	Х	Υ	Ζ	9	0	!	?	,

For entering sentences (name, diagnosis, etc.) the [+] push button moves cursor to the right, acting as a spacebar, and the [-] push button moves the cursor to the left deleting previous characters.

#### 2.2 Instrument Assembly and Initiation

Carefully unpack instrument and place on a sturdy and level surface (max. 15° angle). Place in cool, dry environment out of reach from direct sunlight. Instrument generates heat when in use therefore it should not be placed in the vicinity of other heat generating devices. This may cause overheating of instrument. The instrument is cooled by natural air convection. Do not cover instrument with flammable materials. Do not place instrument in proximity of devices that emit strong eletric, magnetic, or electro-magnetic fields (motors, transformers, X-rays, etc.). This can cause electromagnetic interference. In case of any misunderstanding, please contact your BTL service representative.

Before the INITIAL turning on of instrument, check the Voltage Converter located on the adapter to insure it is in the correct position and in accordance with the mains voltage parameters. Voltage coversion is further described in the chapter Maintenance 2.12. In case of any misunderstanding, please contact your BTL service representative.

We recommend proper storage of the instrument box in case additional transport of instrument is necessary.

The instrument applies irradiation only, it does not apply any pharmaceuticals or substances.

Connecting instrument (DOOR connector on the lower panel) with the door contact is recommended. For further information see **Safety 2.13**.

The power will be ON following the pressing of the mains power switch on the upper panel. When the battary is low, a "**Low battery**" warning will be signalled on the display. It is then necessary to connect the mains power adapter to recharge the battery.

When turning the instrument on you MUST NOT press any buttons on the front panel. This will generate the error sign "Error 100 – Keyboard button jammed". It is then necessary to turn off the instrument for minimum of three seconds to allow it to reset. (See NOTE).

It is now necessary to enter a code to unlock the instrument. The manufacture code is preset as 0000. If it is not modified you can continue by pressing the **[ENTER]** push button. It is possible to change the code using the instructions in the chapter **User diagnoses 2.4.1**. Once the accurate code has been entered, the display shows th main menu. If there are any other reactions after the turning on of the instrument do not attach laser probe and contact BTL service technician before further use.

NOTE: After turning the instrument on and before the entering of the code, the instrument is testing its internal functions (~ 0.5 sec.). If the instrument finds an internal problem, you will see the error notice "Error" and the instrument will then be locked in Safe Mode. In this case, it is necessary to contact your BTL service representative. If the error notification "Error 100 – Keyboard button jammed" is displayed, it is either an operating error or it is possible a button is jammed. In the second case, try to release the affected button or contact your BTL service representative.

## 2.3 Starting Operation

Switch the instrument on by pressing the power switch on the upper panel. Enter the safety code on initial screen.

BTL-2000 THERAPEUTIC LASER ENTER CODE: <u>0</u>000 Using the [+] and [-] arrows, insert the safety code. Use the [TAB] push button to move cursor to the next position. Once the code has been entered, press the [ENTER] push button. The manufacture code is preset as 0000. Press the [ESC/STOP] push button to delete inserted values and to return to the first position.

If the code is entered correctly, the display will show menu which can be preset using the **[Sart with]** function. If the code is not correct, the cursor will move to the first position of the code.

BTL-2000
UNIVERSAL
DIAG PROG
MAN MENU

Use the relative push buttons on the instrument front panel to select from the four programmes on the Main Menu.

#### 2.4 Medical Field Selection (push button [DIAG])

When pressing the **[DIAG]** push button the instrument will enter the Medical Field Menu and it is then possible to select a preset medical field, Acupuncture frequency (Nogier or EAV), or user created programmes.

According to user specialization, there is only one medical field pre-programmed in the instrument. Additional medical fields are available but not included.

User diagnoses
Nogier
EAV
Dentistry
Dermatology
Gynaecology
ENT
Rehabilitation
Neurology
Orthopaedics
Sports medicine
Paediatrics
General Practitioner

Example of medical field menu:

>User diagnoses
Nogier
EAV
Dentistry

Use the [+] or [-] arrows to move between medical fields and press the **[ENTER]** push button to select desired medical field. Press the **[ESC/STOP]** push button to return to the previous menu.

## 2.4.1 User diagnoses

This setting allows searching for and selecting a user diagnoses with preset therapeutic parameters.

If there are no user diagnoses in the memory, "Memory free" will appear on the display.

If there are less than 6 user-created diagnoses in memory, a list of these diagnoses in alphabetical order will appear on the display. If there are 6 or more user-created diagnoses in memory, the following diplay will appear:

USER DIAGNOSES

First char:

Enter the first letter of desired diagnosis name and press the **[ENTER]** push button to enter the list of diagnoses. Use the **[+]** and **[-]** arrows to move between diagnoses names and press the **[ENTER]** push button to select desired diagnosis. After selecting desired diagnosis, preset therapy parameters will be displayed. Press the **[ESC/STOP]** push button to return to previous menu.

**Density** shows set irradiation density value (J/cm<sup>2</sup>)

Frequency shows set frequency (Hz)

**Area** shows set area of irradiated area (cm<sup>2</sup>)

Power shows set laser beam output (mW)

**Time** shows set therapy duration (min/sec)

Use the [+] or [-] arrows to adjust therapy parameters. Use the **[TAB]** push button to move between parameters. Start therapy by pressing the probe push button.

For saving the adjusted parameters use the [MENU] push button to enter patient file or user diagnoses file.

Use the [ESC/STOP] push button to return to previous menu.

## 2.5 Adjusting therapy parameters

When adjusting preset therapy parameters, use the **[MENU]** push button to enter patient files, diagnoses, or user settings.

#### 2.5.1 Density

When the density is adjusted, the instrument automatically recalculates therapy time and power parameters.

## 2.5.2 Irradiated Area

When using a divergent probe, use the following table for the probe distances from skin:

Irradiated area [cm²]	Distance of probe from skin [cm]
0.5	1.5
1	2
1.5	2.5
2	3
2.5	3.5
3	4

When using a divergent probe, depth of penetration changes according to the distance of the probe from skin and it is necessary to deduct the desired depth of penetration from the displayed distance of probe.

When using a convergent probe, distance of the probe from the skin is not a crucial factor. The distance is not measured because the beams are parallel.

#### 2.5.3 Power

When the power is adjusted, the instrument automatically recalculates the duration of exposure. Power value could be adjusted within range 20% to 100% of maximal probe output. Output power and the duration of therapy has an inverse relationship. An increase in power output will result in a decrease in therapy duration. Density will remain the same. The instrument calculates output power in tenths of mW, but the display only shows whole numbers. Maximum and minimum power depends on the type of probe used, preset density and area.

#### 2.5.4 Frequency

When the frequency is adjusted, the instrument automatically recalculates therapy time and power parameters. BTL-2000 offers pre-programmed EAV and Nogier frequencies.

#### 2.5.5 Nogier (Frequencies according to Dr. Nogier)

After entering Nogier frequencies, the list of frequencies will be displayed. Use [+] and [-] arrows to move between the frequencies. Press the **[ENTER]** push button to select required frequency. Press the **[ESC/STOP]** to return to previous menu.

When required frequency is selected, therapy parameters will be displayed:

Use the [+] and [-] arrows to adjust therapy parameters. Use the **[TAB]** push button to move between therapy parameters. Density and area values are preset. Frequencies can be modified only in the range of Nogier's frequencies. Power and time are automatically recalculated. Start therapy by pressing probe push button.

#### 2.5.5.1 Table of frequencies for laser acupuncture according to Dr. Nogier

Frequency [Hz]	Use and Application Area
U 1.14	Universal – whole body
A 2.28	<b>Chaotic changes</b> – tissues and transitional epithelium, body openings (mouth, nose, eyes,)
B 4.56	Nutritive effect – chest and abdominal cavity
C 9.12	Mesenchyma – limbs, gluteal area, muscles and ligaments, kidneys, genitals
D 18.3	Metabolism – joints of cerebral symmetric organs
E 36.5	Nerve tissue –peripheral parts of spine, back and top parts of head and neck
F 73.0	Psychosomatic disorders – subcortical areas, lower parts of the face
G 146.0	<b>Emotional diseases</b> – brain cortex, nervous system, frontal and temporal parts of head, lateral parts of nose

#### 2.5.6 EAV (Frequencies according to Dr. Voll)

After entering EAV, a list of frequencies will be displayed. Use the [+] and [-] arrows to move between the frequencies. Press the [ENTER] push button to select required frequency. Press the [ESC/STOP] push button to return to previous menu. When required frequency is selected, therapy parameters will be displayed:

```
Dens. _2.0J/cm<sup>2</sup>
FrequEncy 1.70Hz
Area 1.0cm<sup>2</sup>Pwr 30mW
Time 1:23 Ready
```

Use the [+] and [-] arrows to adjust therapy parameters. Use the **[TAB]** push button to move between therapy parameters. Density and area values are preset. Frequencies can be modified only in the range of EAV frequencies. Power and time are automatically recalculated. Start therapy by pressing probe push button. Press the **[ESC/STOP]** push button to return to previous menu.

## 2.5.6.1 Table of EAV frequencies EAV (according to Dr.Voll)

Frequency [Hz]	Use and Application Area
1.20	Tachycardia
1.70	Abscess, furunculosis
1.75	Psychostimulative and sympaticostimulative effect
2.20	Fatigue, lipothymia, exhausting, restlessness, melalgia
2.45	Haematoma, oedema, excessive menstrual bleeding due to myoma, haemorrhage of
	varices, sleeplessness, autonomic disorders, sinusitis
2.50	Distorsion, vegetative dystrophia
2.65	Gallbladder dystonia, periostitis
2.90	Rhinitis
3.30	Arteriosclerosis, arteriosclerotic hypertension
3.50	Lithiasis, renal colic, tremor, melancholia
3.60	Sleeplessness, excitability
3.80	Spasms, glossodynia
3.90	Neuralgia, depression, insomnia
4.00	Disorders of pancreas, endocrine disorders, menorrhagia, headaches, dizzeness
4.90	Dysmenorhea, stiff neck
5.55	Angiospasm with paresaesthesia
5.80	Fear, dizzeness, headaches
5.90	Spastic paralysis
6.00	Parasympatikotoic effect, hypertension, spastic stiff neck
6.30	Excitability, headaches
6.80	Myotonia
7.50	Neuralgia n. trigemini
7.70	Spastic paralysis
8.25	Paralysis
9.20	Eczema due to renal insufficiency, diastolic hypertension, renal insufficiency
9.35	Paralysis
9.40	Cystitis, disorders of prostate, disordes of colon, bronchitis, eczema due to disorders of
	lungs or vessles, gout, joint ache, gastric disorders (including ulcer), parsis, varices,
	haemorrhoids
9.45	Tonsillitis, angina pectoris, disorders of hypophysis and gonads
9.50	Spastic hypertension, climacteric hypertension, laryngitis, migraine
9.60	Arthritis, rheumatism, rachiopathies
9.70	Ischialgia, rheumatism
10.00	Flebitis, ulcus cruris

## 2.5.7 Medical Fields

After entering the required medical field, the following menu will be displayed:

DENTISTRY

First char:

Enter the first letter of desired diagnosis name and press the **[ENTER]** push button to enter the list of diagnoses. Use the **[+]** and **[-]** arrows to move between diagnoses names and press the **[ENTER]** push button to select desired diagnosis. After selecting desired diagnosis, preset therapy parameters will be displayed. Press the **[ESC/STOP]** push button to return to previous menu.

```
Dens. _2.0J/cm<sup>2</sup>
Frequency 5.00Hz
Area 1.0cm<sup>2</sup>Pwr 30mW
Time 1:23 Ready
```

Use the [+] and [-] arrows to adjust therapy parameters. Use the **[TAB]** push button to move between therapy parameters. Start therapy by pressing probe push button.

Press the **[ESC/STOP]** push button to return to previous menu.

#### 2.6 Programme selection (push button [PROG])

When pressing the **[PROG]** push button the instrument will enter the Preset Programme Menu. It is then possible to select a preset therapy programme. A programme number consists of a medical field number (first two numbers) and a diagnosis number (second two numbers).

```
Prog 0400
Acne
Dens. 0.4J/cm<sup>2</sup>
Frequency 5.50Hz
```

Use the [+] and [-] arrows to set desired programme number. Use the [TAB] push button to move between the medical field number and diagnosis number. Press the [ENTER] push button to enter therapy parameters of desired programme. Press the [ESC/STOP] push button to return to previous menu. When the desired programme has been entered, therapy parameters will be displayed.

```
Dens. _ 0 . 4 J / c M <sup>2</sup>
Frequency 5 . 0 0 H z
Area 1 . 0 c m <sup>2</sup> P w R 1 6 m W
Time 0:30 Ready
```

Use the [+] and [-] arrows to adjust therapy parameters. Use the **[TAB]** push button to move between therapy parameters. Start therapy by pressing the probe push button. Press the **[ESC/STOP]** push button to return to previous menu.

## 2.7 Manual setting (push button [MAN])

When pressing the **[MAN]** push button, the instrument will enter the Therapy Prameters Menu and it is then possible to set therapy parameters manually.

```
Dens. _1.0J/cm<sup>2</sup>
Frequency Continual
Area 1.0cm<sup>2</sup> Pwr 30mW
Time 0:33 Ready
```

Use the [+] and [-] arrows to adjust therapy parameters. Use the [TAB] push button to move between therapy parameters. Start therapy by pressing the probe push button. Press the [ESC/STOP] push button to return to previous menu.

## 2.8 User menu (push button [MENU])

When pressing the **[MENU]** push button, the instrument will enter the System Menu and it is then possible to select from the following list.

Patient search
Patient list
User diagnoses
System setup
Acupuncture
Probe test

>Patient search
Patient list
User diagnases
System setup

Press the [+] or [-] arrows to move between displayed settings. Press the [ENTER] push button to select desired setting. Press the [ESC/STOP] push button to return to previous menu.

#### 2.8.1 Patient search

Enter Patient Search when searching for patient file with saved therapy parameters. If there is no patient file in memory, "Memory free" will be shown on display. If there are less than 6 patient files in memory, a list of these patient files in alphabetical order will appear on the display. If there are 6 or more patient files in memory, the following menu will be displayed:

PATIENT LIST

First char:

Type the first letter of desired patient name and press the **[ENTER]** push button to enter the list of patients. Use the **[+]** and **[-]** arrows to move between patient names and use the **[ENTER]** push button to select desired patient. After selecting desired patient, patient therapy parameters will be displayed.

Dens. \_0.9J/cm<sup>2</sup>
FrequencY Continual
Area 1.0Cm<sup>2</sup> Pwr 30mW
Time 1:39 Ready

Use the [+] and [-] arrows to adjust therapy parameters. Use the [TAB] push button to move between therapy parameters. Start therapy by pressing the probe push button. Press the [ESC/STOP] push button to return to previous menu.

#### 2.8.2 Patient List

When entering Patient List, the following list will be displayed:

>New patient
Edit patient
Delete patient

Use the [+] and [-] arrows to move between displayed settings. Press the [ENTER] push button to select desired file. Press the [ESC/STOP] push button to return to previous menu.

#### 2821 New Patient

When creating a new patient, enter New Patient by using the **[ENTER]** push button. After entering New Patient, the following menu will be displayed:

```
Patient name:
```

Enter the patient name and press the **[ENTER]** push button to save it in memory. After pressing the **[ENTER]** push button, the therapy parameters will be displayed.

```
Dens. _0.9J/cm<sup>2</sup>
Frequency Continual
Area 1.0cm<sup>2</sup> Pwr 30mW
Time 1:39 Edit
```

Use the [+] and [-] arrows to adjust therapy parameters. Use the **[TAB]** push button to move between therapy parameters. Press the **[ENTER]** push button to save adjusted data. After pressing the **[ENTER]** push button, "**Data saved**" will be shown on the display. Press the **[ESC/STOP]** push button to return to previous menu.

## 2.8.2.2 Edit Patient

Enter Patient Search when searching for patient file with saved therapy parameters. If there is no patient file in memory, "**Memory free**" will be shown on display. If there are less than 6 patient files in memory, a list of these patient files in alphabetical order will appear on the display. If there are 6 or more patient files in memory, the following menu will be displayed:

```
PATIENT LIST

First char:

_
```

Type the first letter of desired patient name. Use the **[ENTER]** push button to enter the list of patients in alphabetical order. Use the **[+]** and **[-]** arrows to move between patient names. Use the **[ENTER]** push button to select desired patient. After selecting desired patient, patient therapy parameters will be displayed.

Dens. \_0.9J/cm<sup>2</sup>
Frequency Continual
Area 1.0cm<sup>2</sup> Pwr 30mW
Time 1:39 Edit

Use the [+] and [-] arrows to adjust therapy parameter. Use the [TAB] push button to move between therapy parameters. Press the [ENTER] push button to save adjusted data. After pressing the [ENTER] push button, "Data saved" will be shown on the display. Press the [ESC/STOP] push button to return to previous menu.

#### 2.8.2.3 Delete Patient

Enter Patient Search when searching for patient file with saved therapy parameters. If there is no patient file in memory, "Memory free" will be shown on display. If there are less than 6 patient files in memory, a list of these patient files in alphabetical order will appear on the display. If there are 6 or more patient files in memory, the following menu will be displayed:

PATIENT LIST

First char:

Type the first letter of desired patient name and press the **[ENTER]** push button to enter the list of patients in alphabetical order. Use the **[+]** and **[-]** arrows to move between patient names and the **[ENTER]** push button to select desired patient. After selecting desired patient, following setting menu will be displayed:

DATA WILL BE DELETED

Continue? Yes

Press the **[ENTER]** push button to delete data. After pressing the **[ENTER]** push button "**Data deleted**" will be shown on the display. Use the **[ + ]** and **[ - ]** arrows to move between the Yes or No settings. Press the **[ESC/STOP]** push button to return to previous menu.

## 2.8.3 User diagnoses

When entering User diagnoses, the following list will be displayed:

>New DIgnosis Edit Diagnosis DeleTE diagnosis

Use the [+] and [-] arrows to move between settings. Press the [ENTER] push button to select desired setting. Press the [ESC/STOP] push button to return to previous menu.

#### 2.8.3.1 New Diagnosis

When creating a new diagnosis, enter New Diagnosis by using the **[ENTER]** push button. After entering New Diagnosis the following menu will be displayed:

```
Therapy name:
```

Enter the diagnosis name and press the **[ENTER]** push button to save it in memory. After pressing the **[ENTER]** push button, therapy parameters will be dispayed.

```
Dens. _0.9J/cm<sup>2</sup>
Frequency Continual
Area 1.0cm<sup>2</sup> Pwr 30mW
Time 1:39 Edit
```

Use the [+] and [-] arrows to adjust therapy parameters. Use the **[TAB]** push button to move between therapy parameters. Press the **[ENTER]** push button to save adjusted data. After pressing the **[ENTER]** push button, "**Data saved**" will be shown on the display. Press the **[ESC/STOP]** push button to return to previous menu.

#### 2.8.3.2 Edit diagnosis

If there are no diagnoses in memory, "**Memory free**" will be shown on display. If there are less than 6 diagnoses in memory, a list of these patient files in alphabetical order will appear on the display. If there are 6 or more patient files in memory, the following menu will be displayed:

```
USER DIAGNOSES

First char:
```

Type the first letter of desired diagnosis name and press the **[ENTER]** push button to enter the list of diagnoses. Use the **[+]** and **[-]** arrows to move between diagnoses and the **[ENTER]** push button to select desired diagnosis. After selecting diagnosis, diagnosis parameters will be displayed.

```
Dens. _0.9J/cm<sup>2</sup>
Frequency Continual
Area 1.0cm<sup>2</sup> Pwr 30mW
Time 1:39 Edit
```

Use the [+] and [-] arrows to adjust therapy parameters. Use the [TAB] push button to move between therapy parameters. Press the [ENTER] push button to save adjusted data. After pressing the [ENTER] push button, "Data saved" will be shown on the display. Press the [ESC/STOP] push button to return to previous menu.

## 2.8.3.3 Delete Diagnosis

If there are no diagnoses in memory, "**Memory free**" will be shown on display. If there are less than 6 diagnoses in memory, a list of these patient files in alphabetical order will appear on the display. If there are 6 or more patient files in memory, the following menu will be displayed:

USER DIAGNOSES

First char:

Type the first letter of desired diagnosis name and press the **[ENTER]** push button to enter the list of diagnoses. Use the **[+]** and **[-]** arrows to move between diagnoses and the **[ENTER]** push button to select desired diagnosis. After selecting diagnosis, following menu will be displayed:

DATA WILL BE DELETED

Continue? Yes

Press the **[ENTER]** push button to delete data. After pressing the **[ENTER]** push button "**Data deleted**" will be shown on display. Use the **[ + ]** and **[ - ]** arrows to move between the Yes or No settings. Press the **[ESC/STOP]** push button to return to previous menu.

#### 2.8.4 System Setup

When entering System Setup, the following list will be displayed:

Entry Code Changes
Backlight
DF (duty factor) Change
Acupuncture Programme
Keyboard Beep
Start with
Language
Door Activity
Battery Formatting
Default Settings

>Entry code change
Backlight
DF change
Acup. progRamme

Press the [+] or [-] arrows to move between displayed settings. Press the [ENTER] push button to select desired setting. Press the [ESC/STOP] push button to return to previous menu.

#### 2.8.4.1 Entry Code Change

The manufacture code is preset as 0000. It is possible to change the code by entering Entry Code Change. After entering Entry Code Change, the following menu will be displayed:

BTL-2000
TERAPEUTIC LASER
ENTER CODE: <u>0</u>000

Enter the preset safety code and press the **[ENTER]** push button. After entering the preset safety code, the following setting menu will be displayed:

BTL-2000
TERAPEUTIC LASER
NEW CODE: 0000

Use the [+] and [-] arrows to enter the new code. Use the [TAB] push button to move cursor to next position. Once the code has been entered, press the [ENTER] push button. After pressing the [ENTER] push button "Data saved" will be shown on display. Press the [ESC/STOP] push button to return to previous menu.

## 2.8.4.2 Backlight

When entering Backlight, the following setting menu will be displayed:

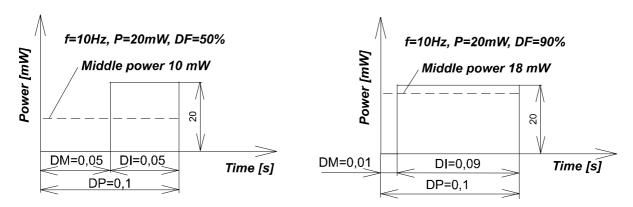
Use the [+] and [-] arrows to adjust backlight intensity. Use the [ENTER] push button to store new data. After pressing the [ENTER] push button "Data saved" will be shown on display. Press the [ESC/STOP] push button to return to previous menu.

Backlight intensity is relative to the energy consumed; the operation time of the battaries is influenced by the backlight intensity. We recommend not setting this intensity too high.

## 2.8.4.3 DF change

If the instrument is operating in pulse mode (it means the frequency is not set to 0) it is possible to adjust the Duty Factor of the output signal. Duty factor (%) defines the ratio of impulse length to period length. The preset value is 80%, and can vary from 10% to 90%. The instrument recalculates the correlating time and power in response to the changing of the mean value of the laser beam. DF value in frequency mode has significant influence on the calculated time. If the time is too long, increase the DF and the time length will automatically decrease. The following figure compares two different duty factors with other conditions being constant. If DF is higher, the laser irradiates a higher mode (average) and the time length shortens.

## 2.8.4.3.1 Comparison of Two Different Duty Factors



After entering the DF change setting, the following menu will be displayed:

Use the [+] and [-] arrows to adjust Duty Factor. Use the [ENTER] push button to store new data. Press the [ESC/STOP] push button to return to previous menu.

#### 2.8.4.4 Acupuncture Programme

After entering the Acupuncture Programme setting, the therapy paramters will be displayed:

Use the [+] and [-] arrows to adjust therapy parameters. Use the [ENTER] push button to store new data. After pressing the [ENTER] push button "Data saved" will be shown on display. Press the [ESC/STOP] push button to return to previous menu.

#### 2.8.4.5 Keyboard Beep

After entering the Keyboard Beep setting, the following menu will be displayed:

Use the [+] and [-] arrows to move between the ON and OFF settings. Use the [ENTER] push button to store new data. Press the [ESC/STOP] push button to return to previous menu.

#### 2.8.4.6 Start With

After entering the Start With setting, the following list will be displayed. From this list it is possible to preset the instruments introductory menu. This menu appears after the entering of the safety code.

Main menu
Diagnoses – Selection according to branches and diagnoses
Program – Selection from the programs menu
Manual – Manual setting
Menu – Selection from menu
Pacient searching

```
>Main
Diag
Prog
Man
```

Use the [+] and [-] arrows to move between Start With settings. Use the **[ENTER]** push button to store new data. After pressing the **[ENTER]** push button "**Data saved**" will be shown on display. Press the **[ESC/STOP]** push button to return to previous menu.

#### 2.8.4.7 Language

After entering the Language setting, the following list will be displayed. From this list it is possible to preset the user language.

English Czech

... (according to default set)

Use the [+] and [-] arrows to move between Cesky / English settings. Use the [ENTER] push button to store new data. Press the [ESC/STOP] push button to return to previous menu.

#### 2.8.4.8 Door Activity

After entering the Door Activity setting, the following menu will be displayed. This programme allows the blocking of the instrument while the door is open.

```
Door Activity
CloSed
```

Use the [+] and [-] arrows to move between the Closed and Open settings. Use the **[ENTER]** push button to store new data. Press the **[ESC/STOP]** push button to return to previous menu.

#### 2.8.4.9 Battery Formatting

Use this setting for the discharging of the NiCd accumulators.

Instrument batteries are NiCd accumulators, therefore it is necessary to format them approximately once every two months according to frequency of use. This function prolongs the lifetime of the accumulators.

Battery formatting
Continue? Yes

Press the [+] or [-] arrows to move between the Yes and No settings. Use the [ENTER] push button to store new data. Press the [ESC/STOP] push button to return to previous menu.

**Warning!** After entering the Yes setting, formatting will begin and the only possibility of terminating formatting is to switch off the instrument. If the mains adapter is not connected, the instrument emits an accoustic signal and "**Connect adapter**" will be displayed.

After discharching, accumulators are automatically recharched. This process lasts approximately 4 hours. In the case of power supply interruption for a period greater than 1 minute, all formatting processes will be restarted after restoration of power supply.

## 2.8.4.10 Default settings

After entering Default Settings, the following menu will be displayed. From this menu it is possible to restore the instruments default settings.

Restore settings
Continue? Yes

Press the [+] or [-] arrows to move between the Yes and No settings. Use the [ENTER] push button to store new data. Press the [ESC/STOP] push button to return to previous menu.

Default setting are as follows:

Keyboard Beep - on
Door Activity - close
Backlight - maximal
Language - English
Acupuncture Program - default values
Battery Capacity - default values

Preset user files, user diagnoses and safety code are not deleted by the restoring of default settings.

## 2.8.5 Acupuncture

The BTL-2000 instrument offers two methods for locating acupuncture points:

1) Locating acupuncture points using probe with acupuncture attachment (not included in standard accesories): Skin resistance is measured by an appropriate course of tension 0.5 V (at 600 kΩ). An acupuncture point can be recognized by a local decrease in skin resistance and can be seen in % on the bar-graph and is accompanied by an accoustic signal. Unscrew the brass cover from the probe head and replace it with the acupuncture attachment. On the lower panel of the instrument, connect the probe with acupuncture attachment to Probe Output (2) and the chrome-plated patient pin to the Acupuncture Output (15). After the acupuncture point is located, press the push button on the probe to begin therapy. This is only possible with Nogier frequencies – see chapter "Performing Therapy".

NOTE: The acupuncture attachment decreases probe aperture approximately 20% resulting in a reduced probe output. The instrument automatically calculates this reduction and corrects the output to a preset laser beam density.

#### 2. Acupuncture Set (not included in standard accesories)

This set contains acupuncture probe with spring-mounted needle, chrome-plated patient pin, and connection cable. This connection cable consists of a connector on one end, identical to the connector of the laser probe and on the other end two different color banana jacks. For measuring acupuncture points, initially connect the connector cable end to **Probe Output (2)**. Attach the reference chromium-plated electrode to the red banana plug, which the patient will hold tight in his/her hand. Attach the acupuncture probe with needle to the green banana plug. This probe contains a special spring that ensures good contact with the skin without using excessive pressure. The instrument will then detect the acupuncture set and begin to measure skin resistance. The resistance of the skin is measured using 0.5 V (600 k $\Omega$ ). This level of generated electricity is directly proportional to the resistance of the skin. The **Bar graph** displays skin resistance in %. As you begin to pass the spring mounted needle over the skin, the acupuncture points are defined by a local decrease in voltage resistance, therefore noticeable by an increased of frequency on the **Bar graph** and an increase in acoustic tone. When the acupuncture point is located, disconnect the needle probe, replace it with the laser probe and desired therapy can be started. The procedure of therapy is described in chapter "**Performing therapy**".

A	CUPUNCTURE	
Probe	$m \circ d$	Auto
0 %	96	30%

Press the [+] a [-] arrows to move between levels of instruments resistance sensitivity. The automatic mode (AUTO) is then changed to (1), (2), (3) or (4). Setting (4) represents the most sensitive setting for patients with very dry skin. Setting (1) represents the least sensitive setting for patients with very wet skin. Use the **[ENTER]** push button to store new data. The therapy parameters will then be displayed:

```
Dens. _0.9J/cm<sup>2</sup>
Frequency ConTinual
Area 1.0cm<sup>2</sup> Pwr 30mW
Time 1:39 REady
```

Press the [+] or [-] arrows to adjust therapy parameters. Press the [TAB] push button to move between therapy parameters. Press the [ENTER] push button to store new data. After pressing the [ENTER] push button "Data saved" will be shown on display. Press the [ESC/STOP] push button to return to previous menu.

#### 2.8.6 PROBE TEST: Optical Power of Probe

This function measures probe output and the status of the probe diode. BTL-2000 automatically tests the probe performance and corrects the power for optimal output (only for the BTL probes).

The warning messages **ATTENTION** and **LASER IRRADIATION** will be displayed followed by the message **PROBE TEST**. Probe parameters will be automatically displayed. Connect probe without cover to the TEST enter on the lower panel of the instrument. Remove the brass cover and insert probe into laser optical power meter "**TEST**" (14). Using probe push button to begin laser emmision. Display will show actual measured probe power, which is dependent on the angle of the probe. Terminate laser emmision using probe push button.

PROBE TEST
Type685nm/30mW
Output26mW

#### 2.9 Therapy

#### 2.9.1 Display during therapy

The instrument continuously checks for laser probe connection. When a probe is connected the parameters of laser therapy will be displayed. In the case that probe is not connected, no therapy parameters will be displayed.

#### Never disconnect probe or switch off instrument while irradiation is in process!

The instrument displays the probe status in the lower right corner of display:

No probe - no probe connected

Ready - instrument ready for irradiation
Wait - period before Ready mode

**In use** - therapy in process

Pause - therapy interrupted by probe push-button (press STOP to cancel)

**Door** - remote control; open door

**Edit** - editing data (names, diagnoses, ...)

## 2.9.2 To start therapy

Irradiation can begin when a probe is attached and **Ready** is signalled in right lower corner on the display. The display shows preset parameters. Take care when handling the probe in order to avoid the unwanted pressing of probe push button. If all parameters are properly set for therapy, hold the probe as you would a pencil and point the laser aperture at the area you want to irradiate. Press the push button on the probe (fig. 1, Appendix A) for one second. When irradiation begins, release the push button and irradiation will continue automatically. Time countdown for the therapy begins when the laser is activated. **In use** is signalled. Each second of irradiation is indicated by a slight ticking sound emitted by the instrument. According to the appropriate therapy, either hold the probe in one place or move it over the designated area at the appropriate distance. When set therapy time has elapsed, the laser automatically stops irradiating and returns to its initial mode.

In case of an emergency situation, switch the laser off by pressing the [ESC/STOP] push button.

#### 2.9.3 To interrupt therapy

#### 2.9.3.1 With the Probe Push button

If the probe push button is pressed during irradiation therapy, the laser switches off and the message "Pause" will be signalled on the display and the instrument will enter PAUSE mode. Continuation of the therapy is possible after pressing the push button on the probe (for two seconds).

Note: Parameters cannot be changed in PAUSE mode. To adjust parameters, press the **[ESC/STOP]** push button and adjust the parameters as needed. Press the probe push button again to reactivate irradiation.

#### 2.9.3.2 Emergency [ESC/STOP] push button

The **[ESC/STOP]** push button functions as an emergency stop. When pressed the laser switches off immediately and therapy stops. Irradiation cannot begin again until the "**Wait**" mode (~ 2 sec.) in completed and the instrument has returned to its initial mode. Pressing the **[ESC/STOP]** push button during a therapy session returns the instrument to its initial mode.

## 2.9.4 To Continue Therapy

If the therapy session is interrupted by pressing the probe push button, press again (for 1 second) to resume therapy. Keep the push button pressed until the probe begins irradiating.

#### 2.9.5 To terminate therapy

Press the probe push button to interrupt therapy and then press the **[ESC/STOP]** push button. The instrument will then return to the same parameters before therapy was initiated.

## 2.10 Power Supply: Mains and Battery

The instrument may be supplied from built-in batteries or from a mains power adapter. Batteries, when fully charged, allow the instrument to function for 6 - 10 hours depending on the number of therapies and probe outputs. If batteries begin to be low, the battery signal in the upper right corner will be displayed. From this moment the instrument guarantees approximately 15 minutes of functioning. This period may be shorter if therapy is performed. When batteries are empty the instrument will automatically switch off. If you want to continue irradiation, attach the mains power adapter and **switch the instrument off and then on**. The instrument is now being supplied by the mains power adapter and the batteries are being recharged.

Recharging is indicated by the battery sign with an arrow (not displayed in some menus). Battery charging is occuring any time the adapter is attached to the instrument, even if the instrument is switched off. There is no risk of overcharging the batteries, when the batteries are fully charged, the charging mode switches to a waiting mode (the

battery sign with an arrow disappears). The recharging cycle of totally empty bateries lasts approximately 260 minutes.

You may continuously switch between mains adapter and batteries; recharging connector may be attached or removed during the use of instrument, without having to switch the instrument off. Nevertheless we recommend to discharge the accumulators completely and the to recharge them. The instrument can be charged overnight without any danger. Use only the original adapter, BTL-282, supplied by the manufacturer.

Accumulators used are NiCd and it is necessary discharge them occasionally (once in 14 days or once in month, depending on how often the instrument is used). Have the instrument switched on until it switches off (e.g., have the instrument on during night and attach the adapter in the morning). This will prolong lifetime of accumulators.

#### 2.10.1 Sparing Batterires

Display lighting decreases continuously when the instrument is not in use. Press any push button on the instrument front panel (not on the probe!) to renew lighted display.

#### 2.11 Optical Attachments

Optical attachments direct laserbeam to treat difficult to reach places. Three optical attachments for dentistry, gynecology and ENT are included with the BTL-2000.

#### 2.11.1 Dentistry Attachment



When using a 685 nm wavelength with the dentistry attachment, it is necessary to increase the density of a preset therapy by 20% and by 10% when using a 830 nm wave length.

## 2.11.2 Gynaecological Attachment



When using a 685 nm wavelength with the gynaecology attatchment, it is necessary to increase the density of the preset therapy by 30 % and by 20 % when using a 830 nm wavelength.

## 2.11.3 ENT Attachment



When using a 830 nm or 685 nm wavelength with the ENT attatchment, it is necessary to increase the density of the preset therapy by 20 %.

Sterilize attachments before each use (water temperature 120°C, time 10 minutes). Do not sterilize plastic cap. Note: The attachments are not included in standard accesorries.

#### 2.11.4 Positioning an Attachment

Unscrew the brass cover from the probe head and replace it with plastic cap. Do not tighten plastic cap until optical attachment is added. Once optical attachment is added, tighten plastic cap to end of probe. To change optical attachments, loosen plastic cap by one turn, exchange optical attachments and retighten plastic cap.

#### 2.12 Maintenance

It is recommended to use and/or store instrument in a dry, dust free environment. Instrument should never be placed in water. Before every use check instrument for damages and if there are damages present do not use.

#### Cleaning the surface of the instrument and its accessories:

Surfaces of the instrument and accessories should be cleaned using a cloth dampened with water or a diluted detergent. Never use chemicals that contain alcohol, ammonia, benzene, thinners, etc..

After each application of a therapy, it is recommended that the laser probe lens be wiped with a cotton cloth. Recommended antiseptic agents: 0.25% - 1% Lysoformin, 2% Sekusept pulver, 2% Chloramin B or 0.5% Persteril. Converting Network Voltage

Electricity converter is located on the front panel of the adapter in a black round case. Before converting network voltage, make sure the mains power switch is turned off. Unplug the power cable from the instrument and from the electrical wall socket. Be sure that the fuses in the instrument are for the voltage needed. See manufacturer label under fuses. In a few cases the correct fuses for the power desired were already installed. With the appropriate screwdriver rotate the switch until the arrow shows the same value as the electrical network. Only qualified personnel should perform this procedure! In case of any misunderstanding, please contact your BTL service representative. The producer of the instrument is not responsible for any damages caused by incorrect voltage conversion. Probe durability

During use period there is aging of laser diode. BTL-2000 measures and displays the laser power on the display. The instrument automatically adjusts to maximum power according to the state of the diode. When the power decreases, due to probe malfunction or diode aging, to less than 40% total power, we recommend replacement of the probe. Instrument manages actual radiation output according to the power of the laser diode. Due to power decrement of optical interfaces inside the probe, the actual power output is lower than stated on the probe label which characterizes the type of probe laser diode.

It is recommended to have the instrument and laser probe tested approximately every 30 months. This must be done by the manufacturer based on the request of the user.

#### Transport and Storage

To avoid damage, transport instrument only in its original packaging. Remove power cable, probe and patient electrodes before packing. Avoid rough handling. Store and transport instrument only under the defined conditions specified in technical parameters.

If item is not functional or repairable it is possible to liquidate under certain circumstances. Item does not contain toxic materials. Disposal of item will not lead to environmental degradation.

## 2.13 Safety of Instrument

## Do not connect non BTL laser probes.

The internal electronics of the BTL-2000 have received the BF Level of Safety certification. The laser and acupuncture probes have also received the BF Level of Safety certification. The producer of these products guarantees the quality of this certification and the quality of these products under the circumstances that only BTL lasers and acupuncture probes are used with this instrument.

## 2.13.1 Remote control (DOOR)

There is remote control connector on the lower panel of the instrument **(DOOR)** (see chapter **Outward Appearance)** for attachment of safety circuit. If the signal on the connector is active (e.g., open door), the instrument will not irradiate. If you attempt to start therapy with the probe push button, the laser will not be turned on and the instrument will go to **Pause** mode. The display will show **Door** accompanied by a sound signal. Any 4.5 - 30 V safety device can be attached to the connector. These are attached between the "door contact signal" and "zero potential" connectors. Electric current needed is approximately 10 mA. Description of Lineouts is on Figure No.3, Appendix A.

## 2.13.2 Use of Safety Accessories

Both therapist and patient are obligated to wear safety eyewear to protect their eyes from laser beam. Safety eyewear must comply with applicable rules and requirements.

#### 2.13.3 Safety Warnings

- Before the initial turning on of the instrument, read manual carefully and observe all operation instructions.
- Check if parameters of electricity correspond with the technical parameters of the instrument and if the voltage switch on the rear panel of instrument is in the correct position in accordance with mains power parameter. If you are not sure whether the electrical network is in optimal condition, an inspection by a certified electrical inspector is required.
- Instrument should be used in proper work environment. It should not be used in an environment where there is danger of explosion and/or water damage.
- During use, storage and transport of BTL-2000, no toxic radiation is emitted.
- The manufacturer or distributor must instruct every user of BTL-2000 regarding service, maintenance, safety principles, and operation of instrument.
- Always place the instrument on a solid, horizontal surface that does not exceed 15 degrees. Cooling vents, located on the rear panel, must at all times be free of obstruction.
- Do not place instrument in proximity of devices that emit strong electric, magnetic, or electro-magnetic fields. (motors, transformers, x rays, etc.). This can cause magnetic interference. In case of any interference, place the instrument further from its source or contact your BTL service representative.
- · Do not place instrument in direct sunlight.
- Only use the instrument if no mechanical or water damage is noticed.
- If instrument is used in discrepancy with this manual or despite functional mistakes noted in this
  manual, the user is responsible for all damages caused by instrument.
- Danger! Removing instrument casing might result in electrical shock!
- All materials and accessories which are in direct contact with patient must be followed by standard health practices to avoid skin harm, allergies, toxicity, genotoxicity, and carcinogenic effects in accordance with ISO 10993-1, ISO 10993-3, ISO 10993-5.
- The user is responsible for the use of materials and accessories that are not supplied by BTL. This includes the cleaning and disinfecting liquids.
- It is advisable to thoroughly check the instrument once a month for loose cables, damaged diodes and damaged display functions.
- It is recommended to have the laser callibrated and the instrument checked for internal malfunctions approximately every 30 months. This must be done by the manufacturer based on the request of the user.
- After application of therapy it is necessary to disinfect probe.
- Do not irradiate sensitive areas such as eyes, head, thyroid gland and other endocrine glands.
- During therapy it is necessary for the patient and the doctor to use the supplied safety eyewear.
- Application of therapy is terminated upon pressing the [ESC/STOP] push button not the mains power switch.
- Between the turning off and turning on of instrument, it is necessary to wait a minimum of 3 seconds.
- Avoid using the instrument in areas that contain flammable and explosive compounds.
- Display warning labels outside the immediate laser workplace. Connect the remote door-blocking device if necessary. Workplace must comply with hygienic standards.
- Do not disconnect the probe or turn the instrument off while irradiating. Do not attatch non-BTL accessories to laser probe or acupuncture connectors.
- Handle probes with care! Probes are not water-resistant.

- Do not remove instrument casing.
- This instrument emits a class 3 B laser beam. During therapy with this instrument, you must follow all
  instructions written in this user manual. Improper therapy manipulation can cause dangerous irradiation
  and damage to eyesight! The manufacturer will not accept responsibility of damage due to improper use
  of the intrument.

For all damages in this case, the user is responsible.

Protect your workplace against direct hit of laser beam.

#### 2.14 Useful addresses

The product is manufactured in accordance with the EU Medical Devices Directive by :

#### BTL Industries Ltd.

Suite 401 Albany House 324-326 Regents Street London, W1B 3BL United Kingdom E-mail: <a href="mailto:sales@btlnet.com">sales@btlnet.com</a> http://www.btlnet.com

For service, please contact service department at service@btlnet.com.

#### 2.15 Warranty

The Manufacturer of this product warrants the product to be free from defects in workmanship and material for a period of twelve months after the date of shipment from the factory. This warranty excludes any disposable items and accessories, including, but not limited to cables or leads, power cords and electrodes. The manufacturer agrees to correct such defects without charge, or at its option to replace the item with a comparable model. To register and be eligible for warranty service, you must send or fax the fully completed warranty registration form within 30 days of installation. All costs of shipment are the responsibility of the purchaser. Damage to any part such as by accident or misuse or improper installation or by use of any accessories or abrasive material not produced by the Manufacturer is not covered by this warranty. Because of varying climatic conditions, this warranty does not cover any changes in finish, including rusting, pitting, corrosion, tarnishing or peeling. Servicing performed by unauthorized persons render this warranty invalid. There is no other express warranty. The Manufacturer hereby disclaims any and all warranties, including but not limited to, those of merchantability and fitness for a particular purpose to the extent permitted by law. The duration of any implied warranty which cannot be disclaimed is limited to the time period as specified in the express warranty. The Manufacturer shall not be liable for incidental, consequential, or special damages arising out of, or in connection with product use or performance except as may be otherwise accorded by law.

This warranty may differ from the warranty terms and conditions provided by your supplier and by applicable laws in your country.

#### 2.16 Accessories

Do not connect non BTL accessories to the instrument.

## 2.16.1 Standard Accessories

Adapter with mains power cable (BTL-282) BTL-2000 – control instrument Warning label Laser Workplace

#### 2.16.2 Additional Accessories

Laser probe with desired power and wavelength Acupuncture set (electrode for patient, locating needle probe) Optical attachments for dentistry, gynaecology and ENT Acupuncture attachment for laser probe Connector for Remote Control Safety eyewear

#### 3 TECHNICAL PARAMETERS

#### 3.1 Technical parameters BTL-2000

**General Parameters** 

- Weight 700g ±50g

**- Dimension** 234 x 132 x 33 mm  $\pm 3\%$ 

- Cover (by EN 60529) IP20

- Class (by EN 60601-1) II (with inner power source and additional external source)

- Class (by 93/42EHS) lib
- Type of applied part BF

- Display LCD display with backlight

- Modes of operations Continual

Operating conditions:

- Temperature10 °C to + 40 °C- Relative humidity30 % to 75 %- Atmospheric pressure700 hPa to 1060 hPa

- Position N/A

Storage conditions

- Temperature- 10 °C to + 55 °C- Relative humidity25 % to 85 %- Atmospheric pressure650 hPa to 1100 hPa

- Position N/A- Maximum Duration 1 year

**Transport conditions** 

- Temperature- 10 °C to + 55 °C- Relative humidity25 % to 85 %- Atmospheric pressure650 hPa to 1100 hPa

- Position N/A- Maximum Duration 1 year

**Power supply** 

- external Adapter BTL-282 (see 3.2 Technical parameters ADAPTER

BTL-282)

**Battery Supply** 

- battery type NiCd accumulator

numbertotal voltagecapacity89.6 V950 mA

- min. operational time 1.5 h (probe 300 mW + backlight)

**Voltage Insulation** 

- Mains Power to Patient Circuit 1.5 kV

Insulation

- Frequency \* \*\*\* 0.0 – 10.0 Hz, step 0.1

11.0 – 100.0 Hz, step 1 110 – 1000 Hz, step 10 1100 – 5000 Hz, step 100

- Standard Deviation  $\pm$  3 % of default value

- **Density** \* 0.1 – 10.0 J/cm2, step 0.1

11.0 - 99.0 J/cm2, step 1

- Pulse

- Standard Deviation ±20% (according to ČSN EN 60601-2-22)

- Area \* 0.1 – 10.0 cm2, step 0.1 11.0 – 99.0 cm2, step 1

- Standard Deviation see beam divergency

- Power Input \* 1.0 − 999 mW, step 1 - Standard Deviation ±20% (ČSN EN 60601-2-22)

- Duty factor \*\* 10-90 %, step 10% - Standard Deviation  $\pm 1\% \text{ of DF range}$ 

Time of Therapy \* 00:05 –99:59, step 1min/1sec  $\pm$  3% - Standard Deviation  $\pm$  3% of adjusted value

**Locating Acupuncture Points**- **Maximum Power of Electrode**Measuring resistance of skin 0.5 V (0.45V typical)

- Voltage Characteristics DC

- Maximum Electrical Current between 5μA (typical 0.5 to 3.5 μA)

- Measurement Ranges
 - Indicators
 4 manual, 3 automatic
 Optic

Measuring Laser Output
- Max. Laser Power Input
- Measuring Ranges

500 mW / max. 15 s
2 – automatic switching

- Standard Deviation  $\pm 15\%$  (ČSN EN 60601-2-22) Laser Probe

- Laser Beam Divergence 0.28 rad ±0.05 rad (Divergent Probe)
- Laser Beam Divergence 0.015 rad ±0.05 rad

(Convergent Probe)

- Laser Class

III.B; III.A, Visible and Invisible light spectrum

- In Compliance with

ČSN EN 60825-1 ČSN EN 60601-2-22

Laser Modes
- Continual

BTL is Designed to Comply with ČSN EN 60601-1

Appendix ČSN EN 60601-1 A2 Appendix ČSN EN 60601-1 A12

ČSN EN 33 4200 ČSN EN 60825-1

Appendix ČSN EN 60825-1 A11

ČSN EN 60601-2-22 ČSN EN 60601-1-2

Emitting laser indicator

Ready for emission indicator

Not ready for emission indicator

Other safety installations

Displayed In use, sound
Displayed Ready, sound
Displayed Wait (safety pause), sound
warning labels on cover and probe

warning labels on cover and probe warning label on workspace door

remote control connector

Power switch positions  $0/1 (1 = \bullet)$ 

#### 3.2 Technical parameters ADAPTER BTL-282

#### **General Parameters**

- Weight – equipment incl. supply cable 0,3 kg  $\pm$  10 % (0,2 kg without supply cable)

- Dimensions (I x w x h) 135 x 72 x 32 mm ±3 %

Cover grade according to EN 60529 IP40Mode of operation Continual

- Indication of operation Green LED on the right, next to the output connector

#### **Operating Conditions**

Ambient temperature
 Relative humidity
 Atmospheric pressure
 Position
 Horizontal on legs

Storage and transport conditions

 $\begin{array}{lll} \text{- Ambient temperature} & \text{- 10 °C to + 55 °C} \\ \text{- Relative humidity} & \text{25 \% to 85 \%} \\ \text{- Atmospheric pressure} & \text{650 hPa to 1100 hPa} \end{array}$ 

- Position N/A

## **Power supply**

- Voltage AC 110V to 230V (±10% tj. ~99V to ~253V)

- Frequency- Input50 Hz - 60 Hz- Max. 42 VA

- Class according to IEC 536

- Inlet type Mini 2 poles

- Fuses (IEC 60127-3/IV) Internal T500mA (can be exchanged only by the manufacturer)

#### Insulation barriers:

mains – output (output cable, plastic 4 kV cover)

## **Output parameters**

- output voltage 13V ± 0,5V; ripple 100mVpp at consumption of 1,5ADC

- output current 1,5A; short-time (max. 10sec) 2A

## Descripton of pictograms on the equipment



applied part of the type BF



equipment with double insulation

<sup>\*)</sup> The stated values are maximum. The actual values depend on the type of the connected laser generator and on the purchased configuration of the equipment.

<sup>\*\*)</sup> Adjustable only in the pulse mode; in the continuous mode it is always 100 %.

<sup>\*\*\*)</sup> The zero frequency means the continuous mode of the laser operation.

<sup>\*\*\*\*)</sup> Frequency is standardly adjustable within the range 0 – 1000 Hz. Upgrade of the frequency range up to 5000 Hz is a part of the above-standard accessories of the equipment.

#### 4 USER'S GUIDE

#### 4.1 Introduction

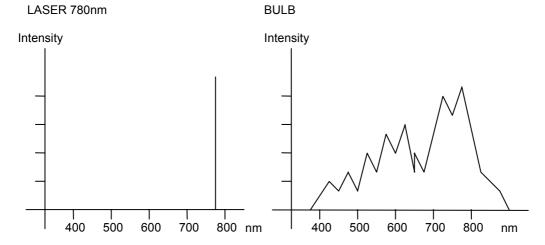
This guide is intended to make you familiar with performing non-invasive laser beam therapy. At the same time, it will give you general instructions on how to perform non-invasive laser beam therapy in clinical practice.

## 4.2 Light; the principle of laser light and its specifics

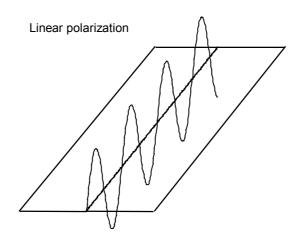
According to classic, relative or quantum physics, the nature and qualities of light can be interpreted in a number of ways. However, the basic nature of light itself as either a particle/corpuscular or an electromagnetic/wave mechanism remains unreachable for our senses and is incomparable to any other levels of reality. Therefore, we can only accept the conclusions and deductions of numerous experiments.

The specifics of laser radiation:

• totally monochromatic: maintaining only one wavelength (e.g., HeNe laser 632.8nm)

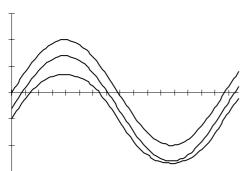


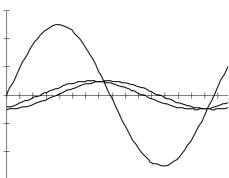
· totally polarized: spatial orientation of the waves on a defined area is absolute



· totally coherent: wavelength orientation in time is absolute, maxima and minima of all waves are identical in time







A laser beam of a high intensity therefore represents the "death ray" of science fiction authors; a laser beam can destroy material or matter. However, a controlled laser beam in low intensities not exceeding 500 mW shows minor effect on living organisms and tissues, but can have significant stimulative effects.

The word LASER stands for Light Amplification by Stimulated Emission of Radiation.

The first theoretical postulates on a laser beam were laid down by Albert Einstein in the early twentieth century, describing the theoretical possibilities of a stimulated emission of light in 1916-1917. However, the first laser instrument was not constructed until 1960, following other important discoveries in the area of the so called quantum radiotechnique (N.G. Basov and A.M. Prochorov of the former USSR and C.H. Townes of the USA received a Nobel Prize for these discoveries in 1964).

The medical application of laser light followed soon after. At first, only high intensity laser beams were utilized. Lasers of this type provide a source of energy that, with its thermal effect, can destroy, cut, evaporate and cauterize tissue.

E. Mester, a Hungarian scientist, was the first to introduce the stimulative effect of a low intensity laser. He conducted his experiments - which are still of a great importance - in the late sixties.

## 4.3 Types of lasers

Lasers can be divided according to several criteria:

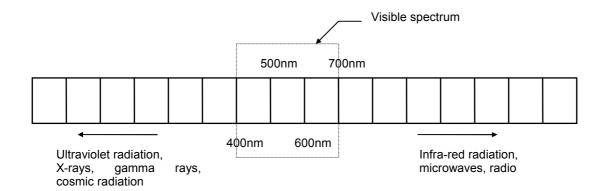
## 4.3.1 Source

- · solid-substance lasers (ruby laser)
- · liquid-based lasers
- gas lasers helium/neon, argon lasers
- semi-conductor (GaAs, GaAlAs) -- the most important form of non-invasive lasers of our time.

The advantages of semi-conductor lasers include a significant miniaturization of the source, robustness and imminstrumenty to damage and the possibility to construct a laser instrument of any wavelength. Nevertheless, some lasers still remain at experimental level.

#### 4.3.2 Wavelength (primarily semi-conductor lasers)

- blue lasers (400-500nm)
- green lasers (500-550nm)
- red lasers (600-700nm)
- infra-red lasers (700-950nm)

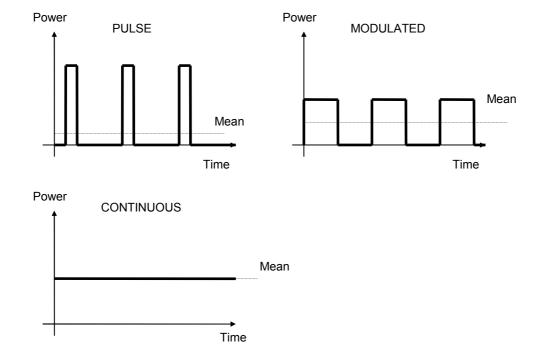


Laser beam penetration through tissue is to a great extent dependent on the wavelength. In general, green and blue lasers are still being developed and their clinical use is extremely limited. Most commonly used are beams in the wavelength of red light. After 2-3mm penetration through living tissue, their intensity is reduced to half. This predetermines red laser beams to be used especially in mucose and skin disease therapy. Since the output is absorbed by a very small column of tissue, devices of 20mW and smaller output are usually fully adequate.

Infra-red lasers intensity is reduced to half after 2-3cm penetration through tissue. These lasers are used especially in treating deep structures (joints, muscles, attachments). Since the output is absorbed by the column of tissue and we want the intensity absorbed by a target area deep in the tissue to be sufficient, we recommend devices of at least 30 mW output.

#### 4.3.3 Operation mode

- pulse lasers: short intervals of radiation emission -- hundreds of ns and top function of the laser is in instruments or tens of watts.
- · continuous lasers: uninterrupted emission of radiation.
- lasers with modulated operation: duration of the pulse depends on frequency and employed substance. Top function of the laser is in instruments through hundreds of mW.



Producers usually offer various alternatives, including the possibility to combine various modes modulated in accordance with various parameters.

#### 4.3.4 Type of beam

- · convergent: a point beam
- divergent: a widening beam that allows irradiation of a larger area without the need to move the probe over the tissue being treated
- · laser scanners: devices for irradiation of large areas

#### 4.3.5 Laser class (defined by the output)

Values described bellow are only for user orientation.

Class 2: less than 1mW

Class 3A (3R, 3M): less than 5mW, output density less than 25 W/m<sup>2</sup>

Class 3B: less than 500mW

#### 4.3.6 Use

- **simple pen lasers**: usually feature only a very limited choice of frequency modes. The advantage of this type of laser is its accuracy.
- **pocket lasers**: designed to fit in the pocket of a physician's gown, and with the probe connected by a cable with the body. These lasers are most common. They may employ probes of tens of mW output.
- **table devices**: usually connected with the mains, and with the probe connected with the device by a cable. The advantages of this type usually include a wide choice of frequency modes and the possibility to set many different parameters.

#### 4.4 Basic physical quantities

- wavelength: one of the basic parameters of a laser beam is that it is always monochromatic. Only one wavelength measured in nanometers (nm).
- output: usually measured in mW. A declared output is either top, i.e. amplitude of pulse, or mean, i.e. average output of the laser. The use of the optic attachment or light conductor causes approximately a 10% loss of output.

It is always necessary to know the output level at the active point of the probe. In lasers where the beam is transmitted by a light conductor, final output can markedly differ from source output! Every transference through a media (air, air-light conductor optic, light conductor optic-air) lowers output.

The mean output also depends on the chosen mode (continuous or pulse). The microprocessor unit checks which mode is employed when counting the therapy time.

- Modulation frequency: declared in the number of oscillations per second Hertz (Hz). Sometimes added are the
  characteristics of the pulses regarding how much % constitutes the active state time (employed substance or
  modulation class) and the width of the pulse. Numeric frequencies are used most commonly (5Hz stimulative,
  10Hz analgesic effect), Nogier frequencies are also used often (previously mainly in acupuncture), and Bahr
  frequencies (acupuncture) and Voll frequencies are also used.
- Power density (dose): (J/cm²) the degree of consistency measured by the quantity of energy emmitted per unit area.

Below you can see a formula for the calculation of emitted dose of energy. (this number is a dose emitted to skin surface, not deeper structures).

#### 4.5 Biologic effects of a low-output laser (non-invasive laser)

Specific physical qualities of a laser beam cause specific clinical effects. The most considerable clinical effects follow:

- analgesic effect
- myorelaxation effect
- antiflogistic effect
- · antiedematous effect
- bactericidal and viricidal effects

All of these effects are based on objective studies that have been validated and verified.

- · quickening of microcirculation
- · increase of intracellular activity of many enzymes, particularly in Krebs cycle
- increased oxygen circulation, improved glucose utilization
- DNA synthesis stimulation (via phytohemaglutinin stimulation)
- increased fibroblast activity (as far as keloids are concerned activated fibroblasts are able to perform a reabsorption of fibrin)
- · phagocytosis activation
- activation of the Na/K pump on the membrane
- activation of metabolic processes in the cellula: partly through the Na/K pump and Ca transport affection, partly through a direct activation of the mitochondrial system
- local level changes of important mediators -- inflammatory (histamin substances, prostaglandins) or e.g., endorphins.

When performing an in vitro experiment, no difference can be seen between laser beams applied in continuous and pulse modes. However, when performing an in vivo experiment, we observe marked differences between a continuous beam and a beam adjusted to a certain defined mode. In physical therapy, this phenomenon can be observed when performing electrotherapy or applying ultrasound. It seems that, as far as a complex organism with its numerous information systems and feedbacks is concerned, a physical quantity modulated to a certain frequency features one additional quality -- specific information transmitted by this frequency.

The effect of laser beam in acupuncture is totally specific. A laser beam affects tissue in a way fully comparable with the effect of an inserted needle -- but without any pain or complications related to needle introduction. The skin above the acupuncture point is a light conductor for the laser beam. We find it interesting that in laser acupuncture, in contrast with other forms of laser therapy, the wavelength of a laser beam is not of a big importance (however, red lasers are slightly more effective) and the output of the device is of no importance at all (we can even use a penlaser). We conclude that, as far as this method of application is concerned, it is not the effect of a physical quantity itself, but the above-mentioned transmission of information that plays the push button role.

Many treatments include several effects of laser light at a time (e.g., treatment of crural ulcer combine analgesic, stimulative, as well as bactericidal effects).

## 4.6 Contradictions of non-invasive laser therapy

- · direct irradiation of glands with intrinsic secretion
- direct irradiation of the eye. Irreversible changes of retina may occur.
- · direct irradiation of malignities and potential pre-cancerous sites
- · febrile patients
- · use of pulse modes or infra-red lenses on patients with seizure diseases such as epilepsy
- · application to the abdomen area during gravidity
- patients with cochlear implants

# 5 LIST OF THERAPIES

# 5.1 Dentistry (Medical Field 03)

	Programme number	Density [J/cm <sup>2</sup> ]	Freq. [Hz]	Comment
Alveolitis	00	3.0	6.0	
Analgia	01	3.5	10.0	
Angulus infectiosus	02	1.6	5.2	
Stomatitis aphtosa (1)	03	3.0	Cont	1 <sup>st</sup> part of therapy
Stomatitis aphtosa (2)	04	3.0	5.2	2 <sup>nd</sup> part of therapy
Caries dentis	05	2.0	3.3	
Cicatrix cheloidum	06	3.0	5.0	
Cicatrix recens (1)	07	4.0	Cont	1 <sup>st</sup> part of therapy
Cicatrix recens (2)	80	4.0	5.0	2 <sup>nd</sup> part of therapy
Contusio	09	3.0	10.0	
Decubitus	10	2.0	6.0	
Dentitio difficillis-analgia	11	3.0	5.0	
Fractura – analgia	12	4.0	10.0	
Gingivitis	13	3.0	5.0	
Herpes (1)	14	3.0	Cont	1 <sup>st</sup> part of therapy
Herpes (2)	15	3.0	5.0	2 <sup>nd</sup> part of therapy
Hyperaemia pulpae	16	4.0	3.5	
Hypersensibilitas	17	2.0	9.0	
dentinalis				
Morbus	18	4.0	9.0	
temporomandibulare				
Neuralgia nervi trigemini	19	2.0	5.0	
Parodontotis	20	3.0	5.0	
Periodontitis	21	4.0	9.0	
Postextractio	22	3.0	10.0	
Preparatio	23	1.0	6.0	
Pulpa aperta	24	4.0	3.5	
Pulpitis	25	3.0	10.0	
Sanatio postoperativa	26	3.0	5.0	

# 5.2 Dermatology (Medical Field 04)

	Programme number	Density [J/cm <sup>2</sup> ]	Freq. [Hz]	Comment
Acne	00	2.0	5.5	
Defluvium capillorum	01	2.0	5.0	
Cicatrix cheloidum	02	3.0	5.0	
Cicatrix recens (1)	03	4.0	Cont	1 <sup>st</sup> part of therapy
Cicatrix recens (2)	04	4.0	5.0	2 <sup>nd</sup> part of therapy
Combustio	05	5.0	9.12	
Decubitus	06	4.0	6.0	
Dermatitis	07	2.0	5.0	
Dermatitis perioralis	08	2.0	5.0	
Eczema	09	2.0	5.0	
Furunculus	10	2.0	2.0	
Haematoma	11	1.0	6.0	
Herpes (1)	12	3.0	Cont	1 <sup>st</sup> part of therapy
Herpes (2)	13	3.0	5.0	2 <sup>nd</sup> part of therapy

	Programme number	Density [J/cm²]	Freq. [Hz]	Comment
Lichen planus	14	2.5	5.0	
Rosacea	15	2.0	5.0	
Sanatio postoperativa	16	3.0	5.0	
Striae	17	3.0	8.4	
Ulcus cruris (1)	18	3.0	Cont	1 <sup>st</sup> part of therapy
Ulcus cruris (2)	19	3.0	5.0	2 <sup>nd</sup> part of therapy

# 5.3 Gynaecology (Medical Field 05)

	Programme number	Density [J/cm <sup>2</sup> ]	Freq. [Hz]	Comment
Abscessus glandulae Bartholini	00	3.0	5.0	
Algomenorrhoea	01	2.0	9.12	
Cervicitis acuta	02	2.5	3.0	
Cervicitis chronica	03	2.0	9.12	
Cicatrix cheloidum	04	3.0	5.0	
Cicatrix recens (1)	05	2.0	Cont	1 <sup>st</sup> part of therapy
Cicatrix recens (2)	06	3.0	4.7	2 <sup>nd</sup> part of therapy
Colpitis acuta	07	1.0	5.0	
Colpitis chronica	08	1.0	9.12	
Conisatio colli uteri	09	1.0	10.0	
Cystitis	10	1.0	3.5	
Dystrophia vulvae (1)	11	1.0	Cont	1 <sup>st</sup> part of therapy
Dystrophia vulvae (2)	12	1.0	5.0	2 <sup>nd</sup> part of therapy
Haematoma	13	1.0	6.0	
Herpes genitalis (1)	14	2.0	Cont	1 <sup>st</sup> part of therapy
Herpes genitalis (2)	15	3.0	4.7	2 <sup>nd</sup> part of therapy
Incontinentia urinae	16	1.0	9.4	
Parametritis	17	2.0	5.5	
Pruritus	18	1.0	5.0	
Sanatio postoperativa	19	1.0	5.0	
Striae	20	0.8	8.4	
Urocystis-irritabilis	21	1.0	9.4	
Vulvitis	22	1.0	5.0	

# 5.4 E.N.T. (Medical Field 06)

	Programme number	Density [J/cm <sup>2</sup> ]	Freq. [Hz]	Comment
Cicatrix recens (1)	00	4.0	Cont	1 <sup>st</sup> part of therapy
Cicatrix recens (2)	01	4.0	5.0	2 <sup>nd</sup> part of therapy
Furunculus	02	2.0	1.7	
Herpes (1)	03	3.0	Cont	1 <sup>st</sup> part of therapy
Herpes (2)	04	3.0	5.0	2 <sup>nd</sup> part of therapy
Otitis media acuta (1)	05	5.0	Cont	1 <sup>st</sup> part of therapy
Otitis media acuta (2)	06	5.0	5.0	2 <sup>nd</sup> part of therapy
Otitis media chronica	07	7.0	5.0	
Perforatio membranae	08	1.6	8.4	
tympani traumatici				
Pharyngitis	09	2.0	5.0	

	Programme number	Density [J/cm²]	Freq. [Hz]	Comment
Rhinitis vasomotorica	10	3.0	4.5	
Sanatio postoperativa	11	2.0	5.0	
Sanatio	12	1.6	5.0	
Posttrepanationis				
Sinusitis acuta	13	5.0	5.0	
Sinusitis chronica	14	2.0	5.0	
Tinnitus (1)	15	10.0	Cont	1 <sup>st</sup> part of therapy
Tinnitus (2)	16	10.0	5.0	2 <sup>nd</sup> part of therapy
Tonsillectomia	17	2.0	9.12	
Tonsillitis	18	5.0	5.0	
Tonsillopharyngitis	19	5.0	5.0	

# 5.5 Rehabilitation (Medical Field 07)

	Programme number	Density [J/cm <sup>2</sup> ]	Freq. [Hz]	Comment
Achillodynie (1)	00	4.0	Cont	1 <sup>st</sup> part of therapy
Achillodynie (2)	01	4.0	10.0	2 <sup>nd</sup> part of therapy
Arthritis	02	4.0	8.6	
Arthritis rheumatica (1)	03	6.0	Cont	1 <sup>st</sup> part of therapy
Arthritis rheumatica (2)	04	6.0	9.12	2 <sup>nd</sup> part of therapy
Arthritis uratica	05	4.0	9.0	
Arthrosis (1)	06	6.0	Cont	1 <sup>st</sup> part of therapy
Arthrosis (2)	07	6.0	10.0	2 <sup>nd</sup> part of therapy
Bursitis (1)	08	4.0	Cont	1 <sup>st</sup> part of therapy
Bursitis (2)	09	4.0	9.12	2 <sup>nd</sup> part of therapy
Calcar calcanei (1)	10	3.0	Cont	1 <sup>st</sup> part of therapy
Calcar calcanei (2)	11	3.0	9.12	2 <sup>nd</sup> part of therapy
Contusio	12	3.0	10.0	
Decubitus	13	4.0	6.0	
Distorsio	14	4.0	10.0	
Enthesopathia	15	5.0	10.0	
Epicondylitis (1)	16	7.0	Cont	1 <sup>st</sup> part of therapy
Epicondylitis (2)	17	7.0	10.0	2 <sup>nd</sup> part of therapy
Chondropathia patelae	18	3.0	10.0	
Induratio penis plastica (1)	19	4.0	Cont	1 <sup>st</sup> part of therapy
Induratio penis plastica (2)	20	4.0	5.0	2 <sup>nd</sup> part of therapy
Ischialgia	21	5.0	9.12	
Morbus Dupuytrene (1)	22	4.0	Cont	1 <sup>st</sup> part of therapy
Morbus Dupuytrene (2)	23	4.0	5.0	2 <sup>nd</sup> part of therapy
Myorelaxatio	24	7.0	10.0	
Oedema	25	2.0	2.4	
Sacralgia	26	10.0	9.12	
Spina dorsalis	27	9.0	Cont	1 <sup>st</sup> part of therapy
(Dorsalgia) (1)				and
Spina dorsalis	28	9.0	10.0	2 <sup>nd</sup> part of therapy
(Dorsalgia) (2)	20	<i>E</i> 0	Cont	1 <sup>st</sup> part of therapy
Spondylarhritis ancylopoetica (1)	29	5.0	Cont	i part or therapy
Spondylarthritis	30	5.0	10.0	2 <sup>nd</sup> part of therapy
ancylopoetica (2) Sy. Canali carpi	31	4.0	9.12	

	Programme number	Density [J/cm <sup>2</sup> ]	Freq. [Hz]	Comment
Sy. Tietz (1)	32	7.0	Cont	1 <sup>st</sup> part of therapy
Sy. Tietz (2)	33	7.0	9.12	2 <sup>nd</sup> part of therapy
Sy. Vertebralis	34	3.0	9.12	
Tendopathia (1)	35	4.0	Cont	1 <sup>st</sup> part of therapy
Tendopathia (2)	36	4.0	10.0	2 <sup>nd</sup> part of therapy
Tendovaginitis (1)	37	4.0	Cont	1 <sup>st</sup> part of therapy
Tendovaginitis (2)	38	4.0	10.0	2 <sup>nd</sup> part of therapy

# 5.6 Neurology (Medical Field 08)

	Programme number	Density [J/cm²]	Freq. [Hz]	Comment
Analgia	00	4.0	10.0	
Calcar calcanei (1)	01	3.0	Cont	1 <sup>st</sup> part of therapy
Calcar calcanei (2)	02	3.0	9.12	2 <sup>nd</sup> part of therapy
Enthesopathia	03	5.0	10.0	
Induratio penis plastica (1)	04	4.0	Cont	1 <sup>st</sup> part of therapy
Induratio penis plastica (2)	05	4.0	5.0	2 <sup>nd</sup> part of therapy
Ischialgia	06	5.0	9.12	
Migraena	07	3.0	9.12	
Morbus Dupuytrene (1)	80	4.0	Cont	1 <sup>st</sup> part of therapy
Morbus Dupuytrene (2)	09	4.0	5.0	2 <sup>nd</sup> part of therapy
Neuralgia	10	3.0	4.56	
Paresis nervi facialis	11	2.0	4.56	
Sacralgia	12	10.0	9.12	
Spina dorsalis	13	9.0	Cont	1 <sup>st</sup> part of therapy
(Dorsalgia) (1)				
Spina dorsalis	14	9.0	10.0	2 <sup>nd</sup> part of therapy
(Dorsalgia) (2)				a4
Tinnitus (1)	15	10.0	Cont	1 <sup>st</sup> part of therapy
Tinnitus (2)	16	10.0	5.0	2 <sup>nd</sup> part of therapy

# 5.7 Orthopaedics (Medical Field 09)

	Programme number	Density [J/cm²]	Freq. [Hz]	Comment
Achillodynie (1)	00	4.0	Cont	1 <sup>st</sup> part of therapy
Achillodynie (2)	01	4.0	10.0	2 <sup>nd</sup> part of therapy
Bursitis (1)	02	4.0	Cont	1 <sup>st</sup> part of therapy
Bursitis (2)	03	4.0	9.12	2 <sup>nd</sup> part of therapy
Calcar calcanei (1)	04	3.0	Cont	1 <sup>st</sup> part of therapy
Calcar calcanei (2)	05	3.0	9.12	2 <sup>nd</sup> part of therapy
Distorsio	06	4.0	10.0	
Epicondylitis (1)	07	7.0	Cont	1 <sup>st</sup> part of therapy
Epicondylitis (2)	80	7.0	10.0	2 <sup>nd</sup> part of therapy
Chondropathia patellae	09	3.0	10.0	
Tendopathia (1)	10	4.0	Cont	1 <sup>st</sup> part of therapy
Tendopathia (2)	11	4.0	10.0	2 <sup>nd</sup> part of therapy
Tendovaginitis (1)	12	4.0	Cont	1 <sup>st</sup> part of therapy
Tendovaginitis (2)	13	4.0	10.0	2 <sup>nd</sup> part of therapy

# 5.8 Sports Medicine (Medical Field 10)

	Programme number	Density [J/cm²]	Freq. [Hz]	Comment
Achillodynie (1)	00	4.0	Cont	1 <sup>st</sup> part of therapy
Achillodynie (2)	01	4.0	10.0	2 <sup>nd</sup> part of therapy
Contusio	02	3.0	10.0	
Distorsio	03	4.0	10.0	
Epicondylitis (1)	04	7.0	Cont	1 <sup>st</sup> part of therapy
Epicondylitis (2)	05	7.0	10.0	2 <sup>nd</sup> part of therapy
Haematoma	06	1.0	6.0	
Myorelaxatio	07	7.0	10.0	
Oedema	08	2.0	2.4	
Tendopathia (1)	09	4.0	Cont	1 <sup>st</sup> part of therapy
Tendopathia (2)	10	4.0	10.0	2 <sup>nd</sup> part of therapy
Tendovaginitis (1)	11	4.0	Cont	1 <sup>st</sup> part of therapy
Tendovaginitis (2)	12	4.0	10.0	2 <sup>nd</sup> part of therapy

# 5.9 Pediatrics (Medical Field 11)

Programme number	Density [J/cm²]	Freq. [Hz]	Comment
00	1.0	5.5	
01	4.0	10.0	
02	1.0	Cont.	1 <sup>st</sup> part of therapy
03	1.0	5.2	2 <sup>nd</sup> part of therapy
04	3.0	5.0	
05	4.0	Cont.	1 <sup>st</sup> part of therapy
06	4.0	5.0	2 <sup>nd</sup> part of therapy
07	5.0	9.12	
08	3.0	10.0	
09	2.0	5.0	
10	2.0	5.0	
11	2.0	2.0	
12	1.0	6.0	
13	3.0	Cont.	1 <sup>st</sup> part of therapy
14	3.0	5.0	2 <sup>nd</sup> part of therapy
15	2.5	5.0	
16	2.0	2.4	
17	1.0	5.0	
18	1.0	5.0	
19	3.0	8.4	
	00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17	number         [J/cm²]           00         1.0           01         4.0           02         1.0           03         1.0           04         3.0           05         4.0           06         4.0           07         5.0           08         3.0           09         2.0           10         2.0           11         2.0           12         1.0           13         3.0           14         3.0           15         2.5           16         2.0           17         1.0           18         1.0	number         [J/cm²]         [Hz]           00         1.0         5.5           01         4.0         10.0           02         1.0         Cont.           03         1.0         5.2           04         3.0         5.0           05         4.0         Cont.           06         4.0         5.0           07         5.0         9.12           08         3.0         10.0           09         2.0         5.0           10         2.0         5.0           11         2.0         2.0           12         1.0         6.0           13         3.0         Cont.           14         3.0         5.0           15         2.5         5.0           16         2.0         2.4           17         1.0         5.0           18         1.0         5.0

# 5.10 General Practitioner (Medical Field 12)

	Programme number	Density [J/cm <sup>2</sup> ]	Freq. [Hz]	Comment
Acne	00	1.0	5.5	
Analgia	01	4.0	10.0	
Stomatitis aphtosa (1)	02	3.0	Cont.	1 <sup>st</sup> part of therapy
Stomatitis aphtosa (2)	03	3.0	5.2	2 <sup>nd</sup> part of therapy
Arthritis	04	4.0	8.6	
Cicatrix cheloidum	05	3.0	5.0	
Cicatrix recens (1)	06	4.0	Cont.	1 <sup>st</sup> part of therapy
Cicatrix recens (2)	07	4.0	5.0	2 <sup>nd</sup> part of therapy

	Programme number	Density [J/cm²]	Freq. [Hz]	Comment
Decubitus	10	4.0	6.0	
Dermatitis	11	2.0	5.0	
Eczema	12	2.0	5.0	
Furunculus	13	2.0	2.0	
Haematoma	14	1.0	6.0	
Herpes (1)	15	3.0	Cont.	1 <sup>st</sup> part of therapy
Herpes (2)	16	3.0	5.0	2 <sup>nd</sup> part of therapy
Lichen planus	17	2.5	5.0	
Oedema	18	2.0	2.4	
Pruritus	19	1.0	5.0	
Sanatio postoperativa	20	1.0	5.0	
Striae	21	3.0	8.4	
Ulcus cruris (1)	22	3.0	Cont.	1 <sup>st</sup> part of therapy
Ulcus cruris (2)	23	3.0	5.0	2 <sup>nd</sup> part of therapy

#### Comment

## 5.11 Acupuncture

Laser beam has a specific effect on acupuncture points, adequate to use of an acupuncture needle. The laser acupuncture has several advantages: it is non-invasive, painless (most patients do report some non-pleasant sensations when acupuncture needle is used), and saves time (usually, several tens of seconds are enough). Very useful is modulation by Nogier frequencies.

For all programmes the following parameters have been preset:

- Duty factor 80%
- Area 1 cm<sup>2</sup>
- Power is calculated according to the probe used

<sup>&</sup>quot;1st part of therapy" and "2nd part of therapy" should be understood as two parts of one therapy session.

## 6 APPENDIX A

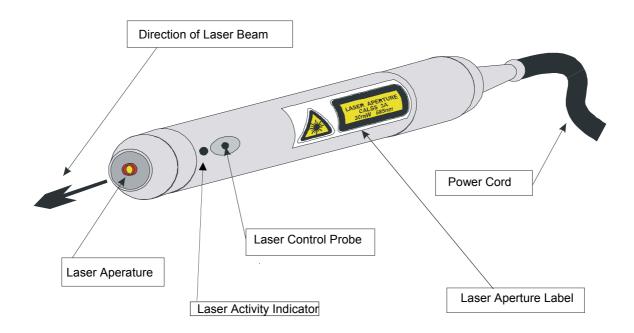


Illustration 1 - Description of LASER PROBE

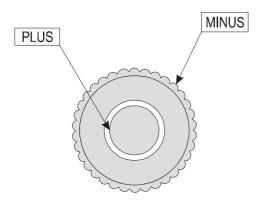
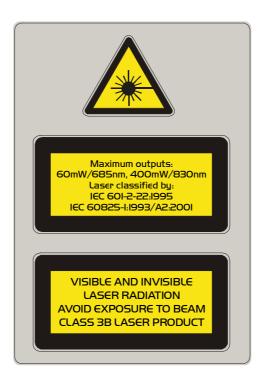
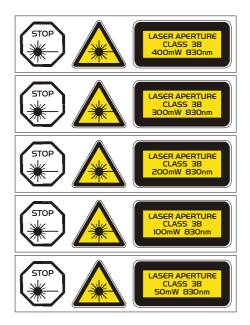


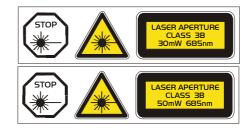
Illustration 2 - Description of REMOTE CONTROL

#### 7 APPENDIX B



Label 1 – This Warning Label is located on rear panel of instrument case. This label states that laser is classified by European Norms. This instrument emits a class 3B laser beam. This laser emits visible and invisible radiation.





Label 2 – This Class and Aperture Label is located on Laser Probe. This label states the laser class, power and wavelength.



Label 3 – Laser Radiation Class III warning label: use in laser therapy room.

This product is manufactured in accordance with the EU Medical Devices Directive by:

## BTL Industries Ltd.

Suite 401 Albany House 324-326 Regents Street London, W1B 3BL United Kingdom

E-mail: <u>sales@btlnet.com</u> <u>http://www.btlnet.com</u>

For service, please contact service department at <a href="mailto:service@btlnet.com">service@btlnet.com</a>.

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